

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

MERCK EPROVA AG

Plaintiff,

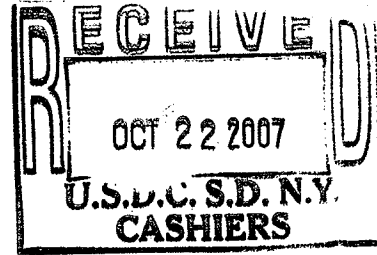
-v.-

GNOSIS S.P.A.

and

GNOSIS BIORESEARCH S.A.

Defendant.



1:07 CV 5898

**FIRST AMENDED COMPLAINT
(JURY DEMAND)**

Plaintiff Merck Eprova AG ("Merck") files this First Amended Complaint against Defendant Gnosis, S.p.A. and Gnosis Bioresearch SA (collectively "Gnosis" or "Defendant") and in support thereof alleges as follows:

NATURE AND BASIS OF ACTION

1. This action arises out of Defendant's knowing and willful false and misleading labeling of its product. Defendant's actions constitute false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(b); contributory false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(b); federal unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a); unfair competition in violation of New York common law; deceptive trade practices in violation of N.Y. Gen. Bus. Law § 349(h); and false advertising in violation of N.Y. Gen. Bus. Law § 350(e)(3). Merck seeks temporary, preliminary and permanent injunctive relief, actual damages, punitive damages, and

recovery of Merck's costs and reasonable attorneys' fees incurred in connection with this action.

THE PARTIES

2. Merck is a Swiss corporation with a principal place of business at Im Laternenacker 5, CH-8200 Schaffhausen, Switzerland.

3. Upon information and belief, Gnosis S.p.A. is an Italian corporation with its principal place of business at Via Lavoratori Autobianchi 1, 20033 Desio (MI) Italy. Gnosis Bioresearch SA, is a Swiss association, with a principal place of business at Via Lischedi, CH-6592 San Antonino, Switzerland.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338 because this case arises under the Lanham Act 15 U.S.C. §§ 1051, *et seq.*

5. This Court has jurisdiction over Merck's state law claims pursuant to 28 U.S.C. § 1367 and the doctrine of supplemental jurisdiction.

6. This Court has personal jurisdiction over the Defendant because the Defendant transacts business within the State of New York, contracts to supply goods or services in the State of New York, and has engaged in tortious acts within the State of New York.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events and injury giving rise to Merck's claims have and continue to occur in this district, and because the Defendant is a foreign person and venue is proper in any District pursuant to 28 U.S.C. § 1391(d).

FACTUAL BACKGROUND

A. Merck, Its Product L-5-MTHF and Its Famous Trademark, METAFOLIN

8. Merck Eprova is the Swiss affiliate of Merck KGaA and provides active pharmaceutical and dietary ingredients to the pharmaceutical and nutritional industry for use in clinical trials and commercial product applications. One such product is marketed in connection with famous and distinctive trademarks consisting in whole or in part of the term METAFOLIN (the “METAFOLIN Marks”).

9. The METAFOLIN Marks have been used by Merck and its customers in connection with the dietary ingredient N-[4-[[[(2-amino-5,6,7,8-tetrahydro-4-hydroxy-5-methyl-(6S)-pteridiny]methyl]amino]benzoyl]-L-glutamic acid, calcium salt, called L-5-methyltetrahydrofolic acid calcium salt (“L-5-MTHF”).

10. Merck filed a New Dietary Ingredient Notification with the FDA in 2001 for its dietary ingredient L-5-MTHF for use in dietary supplements. L-5-MTHF is a source of folate, an essential human vitamin of the B complex.

11. For over 5 years, the dietary ingredient L-5-MTHF has been used in dietary supplements, including, pregnancy vitamins, medical foods, nutritional supplements, and food for special dietary use.

12. The METAFOLIN Marks are owned by Merck KGaA. Merck Eprova has an exclusive license from Merck KGaA to use these METAFOLIN Marks in the United States. Merck KGaA owns Trademark Registration Nos. 3001087 and 2526532 in the United States Patent and Trademark Office for the METAFOLIN Marks.

13. Merck began manufacturing and distributing its L-5-MTHF dietary ingredient in 2002. Since then, Merck and its customers have established a considerable

market in the United States for the product marketed, distributed, imported, and sold. Merck receives substantial revenue from its L-5-MTHF dietary ingredient.

14. Plaintiff Merck is the sole importer, licensor, and primary distributor of the bulk substance L-5-MTHF in the United States, directly and through its licensees. Merck supplies L-5-MTHF as a bulk substance. Merck's customers use METAFOLIN brand L-5-MTHF in various dietary supplements, medical foods, nutritional supplements, pregnancy vitamins, and food for special dietary use. The presence of genuine L-5-MTHF is used by Merck's customers as a unique selling point. Merck distributes, as well as, licenses METAFOLIN brand L-5-MTHF to its customers.

15. Merck has conducted extensive clinical and laboratory trials and testing on its L-5-MTHF.

16. The unique benefits of L-5-MTHF come from the fact that it consists of a single diastereoisomer of the compound 5-methyltetrahydrofolic acid and the fact that it is a stable crystalline product.

17. Many products, such as 5-methyltetrahydrofolic acid, naturally occur as mixtures of two or more diastereoisomers.

18. The various diastereoisomers that are present in such mixtures can have radically different properties from one another. In some cases, one diastereoisomer can have a therapeutic effect, while another diastereoisomer is therapeutically ineffective. In the most severe instances, one diastereoisomer may be highly toxic while another diastereoisomer may have incredible pharmacological utility. Thus, there are often great benefits to providing patients and consumers with a product that contains only a single diastereoisomer as opposed to a diastereoisomeric mixture.

19. Diastereoisomers are distinguished from one another through naming conventions that reflect their different properties. One such naming convention uses a "D" in the name of the compound for one diastereoisomer and an "L" in the name of the compound to indicate a different diastereoisomer.

20. The product 5-methyltetrahydrofolic acid is a mixture of two diastereoisomers, the "L-form" and the "D-form."

21. The L-form (i.e., L-5-MTHF) is highly preferable to the D-form (i.e., D-5-MTHF) because the L-form is the naturally occurring predominant form of folate found in food and the human body. The L-form is the biologically active form of folate and has proven to have a high degree of bioavailability (the rate at which a drug or other substance is available at the targeted place in the body) in humans. In contrast, the D-form, is an unnatural form of folate, which humans are unable to metabolize.

22. L-5-MTHF is the pure diastereoisomeric form of folate used by cells in the body. In humans, this particular compound is the predominant form in circulation and transport into the tissues, and it is the only folate that can cross the blood-brain barrier.

23. In fact, because the D-form exhibits virtually no beneficial activity, the presence of any of the D-5-MTHF diastereoisomer could compete with the uptake and activity of the L-5-MTHF diastereoisomer and therefore reduces the overall usability of the compound.

24. Merck's L-5-MTHF complies with all applicable requirements for dietary ingredients established by the United States Food and Drug Administration ("FDA").

25. Over the years, Merck has spent many millions of dollars researching and developing its L-5-MTHF, and devotes significant financial resources each year to marketing its product.

26. Defendant is in no way affiliated with Plaintiff Merck or its related entities.

27. Merck is acclaimed worldwide for its novel drugs and therapeutic products.

28. Merck's products are some of the most well-known and well-respected medical and dietetic products worldwide.

29. Over the years, Merck has worked hard to expand and to build its trade name, trademarks and products.

30. Merck has over the years worked extremely hard to ensure that the quality of the Merck product L-5-MTHF is extraordinarily high and that this product is of the highest safety and efficacy.

31. For example, Merck conducted countless experiments and tests to determine the safety and efficacy of its L-5-MTHF, and spent years and millions of dollars on research and development to discover and perfect the product.

B. Defendant's Unlawful Conduct

32. Upon information and belief, Defendant is a manufacturer, distributor and supplier of nutritional dietary ingredients, among other things.

33. Through its agents, Gnosis sells and distributes its products worldwide, including sale and distribution into the United States and into New York State, in particular.

34. Gnosis sells the dietary ingredient, 5-MTHF, the diastereoisomeric mixture, which it has falsely labeled and continues to falsely label as the pure L-5-MTHF diastereoisomer (the "Gnosis Compound").

35. That Gnosis mislabels its product by using the L-5-MTHF label is readily apparent because Gnosis fails to follow standard labeling language that has been approved by the FDA. Specifically, the FDA issued a New Dietary Ingredient Notification ("NDI") for another company seeking to use and market 5-MTHF, the identical ingredient that makes up the Gnosis Compound. The NDI stated that the requesting company must label its product as "methyltetrahydrofolate" or "5-MTHF." Thus, FDA ruling establishes that it is improper to label Gnosis's 5-MTHF product as L-5-MTHF.

36. In October 2006, Merck was first alerted to the fact that Defendant was distributing and actively marketing a product which Defendant claimed was L-5-MTHF in countries such as the United States and Germany.

37. The website of Denk Feinchemie GmbH (www.denk-feinchemie.de), international distributors of raw materials, provided as of October, 2006 that Gnosis was the manufacturer of L-5-MTHF, specifically L-5-Methyltetrahydrofolic acid calcium salt.

38. In a press release dated April 10, 2007, Gnosis announced that it was entering into a new distribution agreement with a UK-based company for the sale of Gnosis products in the United Kingdom and Ireland. One of the products subject to the agreement is Extrafolate, which, according to the press release of Gnosis, is allegedly L-5-Methyltetrahydrofolic acid and calcium salt.

39. Upon information and belief, Gnosis is providing the Gnosis Compound to be marketed as Extrafolate.

40. Gnosis has provided the Gnosis Compound to other distributors, including AHD International LLC ("AHD"), a Georgia corporation.

41. Merck filed suit against AHD in the Northern District of Georgia, Case No. 1:07 CV-0597 ("the AHD Action"), for, *inter alia*, falsely labeling its ingredient as the pure L-5-MTHF diastereoisomer, when, in fact, that ingredient contained the diastereoisomeric mixture 5-MTHF and not pure L-5-MTHF.

42. As part of a settlement agreement in the AHD Action, AHD has since ceased selling and advertising 5-MTHF, however, not before revealing that its diastereoisomeric mixture product was manufactured and supplied by Gnosis.

43. Merck has obtained samples of the Gnosis Compound and performed analytical tests to determine the composition of the Gnosis Compound.

44. These tests concluded that the Gnosis Compound is not pure L-5-MTHF, but is instead the diastereoisomeric mixture 5-MTHF.

45. Also as part of that settlement agreement in the AHD Action, AHD provided Merck with copies of the certificates of analysis that AHD received from Gnosis for the 5-MTHF product AHD received from Gnosis.

46. Those certificates of analysis, product labels, and product specification, which Gnosis provided to AHD and to its other customers, falsely claim that the Gnosis Compound is pure L-5-MTHF when, in fact, it is not.

47. Gnosis has knowledge that the Gnosis Compound is the diastereoisomeric mixture 5-MTHF and not the pure L-5-MTHF diastereoisomer.

48. Gnosis has admitted to Merck on multiple occasions, directly and through outside counsel, that the Gnosis Compound is the diastereoisomeric mixture 5-MTHF and not the L-5-MTHF diastereoisomer.

49. Despite these admissions, Gnosis continues to falsely represent to its distributors and the consuming public that the Gnosis Compound consists only of the pure L-5-MTHF diastereoisomer.

50. Upon information and belief, through materials accessible through the internet and through materials distributed to customers and potential customers, Gnosis has marketed its diastereoisomeric mixture 5-MTHF product as the pure L-5-MTHF diastereoisomer in an effort to induce customers to believe that the Gnosis Compound was genuine L-5-MTHF, when it is not, or to believe that the Gnosis Compound is equivalent to L-5-MTHF, when it is not.

51. Gnosis has performed the aforementioned acts globally, as well as within the United States and the State of New York.

52. Gnosis is deliberately misrepresenting to consumers, the public and the marketplace that the Gnosis Compound has the same efficacy and safety as Merck's proprietary L-5-MTHF, when, in fact, the two products are not the same and do not have the same therapeutic effect.

53. Upon information and belief, Gnosis knew that its customers were improperly labeling the Gnosis Compound as L-5-MTHF and allowed and encouraged the customers to label the Gnosis Compound as L-5-MTHF, despite it being the diastereoisomeric mixture 5-MTHF.

54. Gnosis has advertised that the Gnosis Compound is a pure diastereoisomer and of the highest quality, when, in fact, it is not.

55. The Gnosis Compound is marketed as a competing product to genuine L-5-MTHF.

56. The public's use of the Gnosis Compound will have inferior therapeutic results as compared to L-5-MTHF and will cause consumers to doubt the overall efficacy of all L-5-MTHF products.

57. Any of the above results could expose the general public, including the United States and New York consumers, to dangerous medical implications.

58. The distribution and sale of the Gnosis Compound has and will continue to cause Merck to lose sales of its genuine L-5-MTHF to both existing Merck customers and to potential customers.

59. The association of the Gnosis Compound as genuine L-5-MTHF is likely to tarnish the reputation of both Merck and its L-5-MTHF in that the Gnosis Compound fails to provide the expected level of purity and is far inferior to L-5-MTHF.

COUNT I

FALSE ADVERTISING

60. Merck incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 59 above, inclusive.

61. Defendant's statements made to the press, statements made on the internet, advertising and promotions, and labeling of the Gnosis Compound, which state that the Gnosis Compound is composed of the pure L-5-MTHF diastereoisomer, are materially false statements that are likely to cause consumer confusion, mistake, or deception as to

the quality and reliability of the Gnosis Compound. These are material misrepresentations upon which customers or potential customers have, and will rely. Defendant's actions therefore mislead and harm customers and consumers as well as damage Merck's good name and reputation in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

62. Defendant's distribution of certificates of analysis which state that the Gnosis Compound is the pure L-5-MTHF diastereoisomer are materially false statements that are likely to cause consumer confusion, mistake or deception as to the quality and reliability of the Gnosis Compound. These are material misrepresentations upon which customers or potential customers have and will rely. Defendant's actions, therefore, mislead and harm customers and consumers as well as damage Merck's good name and reputation in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

63. Given Gnosis's knowledge and admissions that the Gnosis Compound is the diastereoisomeric mixture 5-MTHF, and not the pure L-5-MTHF diastereoisomer, the aforesaid acts were undertaken willfully and deliberately and with the intention of causing confusion, mistake, or deception.

64. The aforesaid acts of Defendant have caused, and will continue to cause, damage to Plaintiff in an amount to be determined at trial.

65. The aforesaid acts of Defendant have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Plaintiff for which Plaintiff has no adequate remedy at law.

COUNT II

CONTRIBUTORY FALSE ADVERTISING

66. Merck incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 65 above, inclusive.

67. Defendant has falsely told its distributors that the Gnosis Compound is the pure L-5-MTHF diastereoisomer.

68. Upon information and belief, Defendant has provided false certificates of analysis, product labels and product specifications, to its distributors which state that the Gnosis Compound is the pure L-5-MTHF diastereoisomer.

69. Defendant induced its distributors to engage in false advertising by labeling and marketing the Gnosis Compound as the pure L-5-MTHF diastereoisomer.

70. Defendant knew or had reason to know that its distributors would engage in false advertising by labeling and marketing the Gnosis Compound as the pure L-5-MTHF diastereoisomer.

71. As a result, Gnosis's distributors made materially false statements that are likely to cause consumer confusion, mistake, or deception as to the quality and reliability of the Gnosis Compound. These are material misrepresentations upon which customers or potential customers have and will rely. Defendant's actions, therefore, caused its distributors to mislead and harm customers and consumers as well as damage Merck's good name and reputation in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

72. Given Gnosis's knowledge and admissions that the Gnosis Compound is the diastereoisomeric mixture 5-MTHF and not the pure L-5-MTHF diastereoisomer, the

aforesaid acts were undertaken willfully and deliberately and with the intention of causing confusion, mistake, or deception.

73. The aforesaid acts of Defendant have caused, and will continue to cause, damage to Plaintiff in an amount to be determined at trial.

74. The aforesaid acts of Defendant have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Plaintiff for which Plaintiff has no adequate remedy at law.

COUNT III

USE OF FALSE DESCRIPTIONS AND FALSE REPRESENTATIONS

75. Merck incorporates herein and realleges, as if fully set forth in this paragraph, the allegations of paragraphs 1 through 74 above, inclusive.

76. Defendant's statements made to the press, statements made on the internet, advertising and promotions, and labeling of the Gnosis compound, which state that the Gnosis Compound is the pure L-5-MTHF diastereoisomer, are materially false statements that misrepresent the nature, characteristics, and quality of the Gnosis Compound.

77. Defendant's distribution of certificates of analysis, which state that the Gnosis Compound is the pure L-5-MTHF diastereoisomer, are materially false statements that misrepresent the nature, characteristics, and quality of the Gnosis Compound.

78. Such materially false statements have caused and are likely to continue to cause consumer confusion, mistake, or deception as to quality and reliability of the Gnosis Compound.

79. Gnosis, therefore, has willfully promoted the Gnosis Compound in interstate commerce so as to cause confusion or mistake among the public as to the

quality and content of the Gnosis Compound, all to Gnosis's profit and the public's and Merck's damage.

80. Given Gnosis's knowledge and admissions that the Gnosis Compound is the diastereoisomeric mixture 5-MTHF and not the pure L-5-MTHF diastereoisomer, the aforesaid acts were undertaken willfully and deliberately.

81. The aforesaid acts of Gnosis constitute use of false descriptions and false representations in interstate commerce in violation of § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

82. The aforesaid acts of Gnosis have caused, and will continue to cause, damage to Plaintiff in an amount to be determined at trial.

83. The aforesaid acts of Defendant have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Plaintiff for which Plaintiff has no adequate remedy at law.

COUNT IV

COMMON LAW UNFAIR COMPETITION

84. Merck incorporates herein and realleges, as if fully set forth in this paragraph, the allegations of paragraphs 1 through 83 above, inclusive.

85. Gnosis has made false statements to the public and its customers and has mislabeled the Gnosis Compound with the intent of deceiving and misleading the public as to the quality and nature of its product.

86. The aforesaid acts have enabled Gnosis to misappropriate the labors and expenditures of Merck in developing the market for the pure L-5-MTHF diastereoisomer.

87. Additionally, the aforesaid acts have caused, and are likely to continue to cause injury to the public and to Merck's business representation, and result in Gnosis unfairly competing with Merck.

88. Given Gnosis's knowledge and admissions that the Gnosis Compound is the diastereoisomeric mixture 5-MTHF and not the pure L-5-MTHF diastereoisomer, the aforesaid acts were undertaken willfully and deliberately.

89. The aforesaid acts of Defendant have caused, and will continue to cause, damage to Plaintiff in an amount to be determined at trial.

90. The aforesaid acts of Defendant have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Plaintiff for which Plaintiff has no adequate remedy at law.

COUNT V

DECEPTIVE TRADE PRACTICES IN VIOLATION OF N.Y. GEN. BUS. LAW § 349(H)

91. Merck incorporates herein and realleges, as if fully set forth in this paragraph, the allegations of paragraphs 1 through 90 above, inclusive.

92. Gnosis has been and is engaging in willful deceptive acts or practices in New York against Merck and the public in the conduct of its business through the following consumer-oriented acts: making false and misleading statements in press releases; making false and misleading statements on the internet; making false and misleading commercial advertising or promotions; mislabeling the Gnosis Compound as the pure L-5-MTHF diastereoisomer; and providing false and misleading certificates of analysis and product specification, all of which, upon information and belief, materially misrepresent the nature, characteristics and qualities of the goods and services associated

with the Gnosis Compound. The aforesaid acts of Gnosis are in violation of N.Y. Gen. Bus. Law § 349(h).

93. The aforesaid misleading acts of Gnosis have additionally caused, and are likely to continue to cause injury to the public, including consumers in New York, and injury to Merck's business reputation.

94. Gnosis's acts have caused, and unless restrained by this Court, will continue to cause, great and irreparable damage to the public and to Merck's business and goodwill for which Merck and the public have no adequate remedy at law.

95. As a result of Gnosis's willful and intentional misconduct, Merck and the public are therefore entitled to appropriate relief as prayed for hereinafter, including preliminary and permanent injunctive relief.

96. Moreover, Gnosis's willful and knowing violation of Section 349(h) warrants treble damages and the recovery of attorneys' fees.

COUNT VI

FALSE ADVERTISING IN VIOLATION OF N.Y. GEN. BUS. LAW § 350(E)(3)

97. Merck incorporates herein and realleges, as if fully set forth in this paragraph, the allegations of paragraphs 1 through 96 above, inclusive.

98. Gnosis has been and is engaging in false advertising in New York against Merck and the public in the conduct of its business through the following consumer-oriented acts: making false and misleading statements in press releases; making false and misleading statements on the internet; making false and misleading commercial advertising or promotions; mislabeling the Gnosis Compound as the pure L-5-MTHF diastereoisomer; and providing false and misleading certificates of analysis and product

specification, all of which, upon information and belief, materially misrepresent the nature, characteristics and qualities of the goods and services associated with the Gnosis Compound. The aforesaid acts of Gnosis are in violation of N.Y. Gen. Bus. Law § 350(e)(3).

99. The aforesaid false statements of Gnosis have additionally caused, and are likely to continue to cause injury to the public, including consumers in New York, and injury to Merck's business representation.

100. Gnosis's acts have caused, and unless restrained by this Court, will continue to cause, great and irreparable damage to the public and to Merck's business and goodwill for which Merck and the public have no adequate remedy at law.

101. As a result of Gnosis's willful and intentional misconduct, Merck and the public are therefore entitled to appropriate relief as prayed for hereinafter, including preliminary and permanent injunctive relief.

102. Moreover, Gnosis's willful and knowing violation of Section 350(e)(3) warrants treble damages and the recovery of attorneys' fees.

JURY DEMAND

MERCK demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Merck respectfully prays for the following relief:

A. The Court enter judgment that Defendant, as a result of its willful, deliberate, and materially false statements regarding the quality and content of its product has: engaged in false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(b); engaged in contributory false advertising in violation of Section

43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(b); engaged in federal unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a); engaged in unfair competition in violation of New York common law; engaged in deceptive trade practices in violation of N.Y. Gen. Bus. Law § 349(h); and engaged in false advertising in violation of N.Y. Gen. Bus. Law § 350(e)(3).

B. The Court issue temporary, preliminary, and permanent injunctions ordering Defendant to, *inter alia*, immediately cease all distribution and sale of the Gnosis Compound;

C. The Court order a recall of all of the Gnosis Compound currently in the marketplace;

D. The Court order a recall of all products containing the Gnosis Compound currently in the marketplace;

E. The Court order that Gnosis engage in a program of corrective advertising, satisfactory to Merck, to ameliorate the false and misleading information that Gnosis has promulgated;

F. The Court grant an award of damages in an amount sufficient to compensate Merck for injury it has sustained as a consequence of Defendant's unlawful acts;

G. The Court grant an award of treble damages;

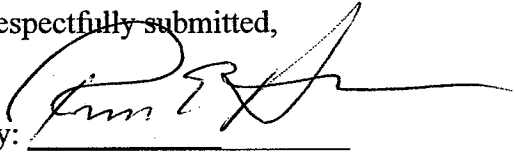
H. The Court grant an award of punitive damages in an amount sufficient to punish and deter Defendant from engaging in further knowing acts of unfair competition;

I. The Court grant the costs of this action and the reasonable attorneys' fees Merck incurs in connection with this action; and

J. The Court grant such other, different, and additional relief as the Court deems just and proper.

Dated: October 22, 2007

Respectfully submitted,



By: _____

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